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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,736	09/11/2000	James M. Zavislan	ML-0414DIV	3878

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KENNETH J. LUKACHER
SOUTH WINTON COURT
3136 WINTON ROAD SOUTH, SUITE 301
ROCHESTER, NY 14623

EXAMINER

SMITH, RUTH S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,736

Applicant(s)

ZAVISLAN, JAMES M.

Examiner

Ruth S. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 19-23, 26-36 and 42-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 5 and 7 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8, 19, 20, 23, 26-36 and 42-51 is/are rejected.
- 7) ☒ Claim(s) 21 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/3/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/06 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,19,26-34,42-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Zavislan et al (5,788,639).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Zavislan et al disclose a system for examining the skin of a patient. The system includes a plate 20 pressed into contact against the skin and movable optics to adjust the focus at which the light is focused. The means for pressing the plate against the

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skin would inherently include means for maintaining the position of the plate with respect to the patient.

Claims 49,50 are rejected under 35 U.S.C. 102(b) as being anticipated by Dhawan. Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54. The opening in the platen 54 includes a material window as part of element 44. The element 54 is positionable against tissue and it by itself does not apply a suctioning force.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,19,26,29,31-33,42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corcuff et al ("In Vivo Vision of the Human Skin with the Tandem Scanning Microscope") in view of Zavislan et al. Corcuff et al disclose the use of a confocal microscope to provide images representing optically formed sections. Corcuff et al disclose the microscope is modified to limit skin movements using a surface contact device. The surface contact device is considered to be a plate through which light passes. The device will inherently apply force and maintain an area of skin tissue under stress. The device will inherently apply force against at least the edges of the area of skin tissue being examined. Zavislan et al disclose a system for examining the skin of a patient. The system includes a plate 20 pressed into contact against the skin and movable optics to adjust the focus at which the light is focused. It would have been obvious to one skilled in the art to have modified Corcuff et al such that it includes

movable optics to adjust the focus at which the light is focused. The advantage of such is to be able to examine skin at different locations.

Claims 1,2,6,8,19,26-36,42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corcuff et al in view of Dhawan and Zavislan et al. Corcuff et al disclose the use of a confocal microscope to provide images representing optically formed sections. Corcuff et al disclose the microscope is modified to limit skin movements using a surface contact device. The device will inherently apply force and maintain an area of skin tissue under stress. The device will inherently apply force against at least the edges of the area of skin tissue being examined. Corcuff et al fails to disclose that the means for maintaining the skin under stress comprises a platen and a movable objective lens. Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44 which is considered to be a plate. Placement of the platen with respect to the tissue to be imaged inherently includes the means for moving it into position as set forth in claim 2. It would have been obvious to one skilled in the art to have modified Corcuff et al such that the means for maintaining the skin under stress is as taught by Dhawan. Such a modification involves the substitution of one known means for maintaining the skin under stress by application of force in the environment of an optical imaging camera for another. With respect to claim 6, Corcuff et al discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head in the modified Corcuff et al device would have been an obvious design choice to one skilled in the art. Zavislan et al disclose a system for examining the skin of a patient. The system includes a plate 20 pressed into contact

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against the skin and movable optics to adjust the focus at which the light is focused. It would have been obvious to one skilled in the art to have further modified Corcuff et al such that it includes movable optics to adjust the focus at which the light is focused. The advantage of such is to be able to examine skin at different locations.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corcuff et al in view of Dhawan and Zavislan et al as applied to claim 2 above, and further in view of Jester et al, "In Vivo, Real-time Confocal Imaging". Jester et al disclose means for fixing the position of the imaging device with respect to an area of the patient before it is lowered into place on the patient. It would have been obvious to one skilled in the art to have further modified Corcuff et al such that it includes means for temporarily fixing the imaging with respect to the patient before it is moved into contact with the tissue. Such a modification allows for more precise positioning and handling of the device. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head in the modified Corcuff et al device would have been an obvious design choice to one skilled in the art.

Claims 20,23,51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corcuff et al in view of Dhawan and Jester et al, "In Vivo, Real-time Confocal Imaging". Corcuff et al which disclose the use of a confocal microscope to provide images representing optically formed sections. Corcuff et al disclose the microscope is modified to limit skin movements using a surface contact device. The device will inherently apply force and maintain an area of skin tissue under stress. The device will inherently apply force against at least the edges of the area of skin tissue being examined. Corcuff et al fails to disclose that the means for maintaining the skin under stress comprises a platen. Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a

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platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Placement of the platen with respect to the tissue to be imaged inherently includes the means for moving it into position as set forth in claim 2. It would have been obvious to one skilled in the art to have modified Corcuff et al such that the means for maintaining the skin under stress is as taught by Dhawan. Such a modification involves the substitution of one known means for maintaining the skin under stress by application of force in the environment of an optical imaging camera for another. Jester et al disclose means for fixing the position of the imaging device with respect to an area of the patient before it is lowered into place on the patient. It would have been obvious to one skilled in the art to have further modified Corcuff et al such that it includes means for temporarily fixing the imaging with respect to the patient before it is moved into contact with the tissue. Such a modification allows for more precise positioning and handling of the device. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head in the modified Corcuff et al device would have been an obvious design choice to one skilled in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,19,26,29-34,42,43-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2,6,8-18 of U.S. Patent No. 6,937,886 in view of Zavislan et al (5,788,639). Zavislan et al disclose the use of movable optics in a confocal imaging system that allows one to change where the light is focused and therefore where the images are formed. It would have been obvious to one skilled in the art to have modified the claimed invention as set forth in 6,937,886 such that it includes movable optics for changing where the light is focused.

Allowable Subject Matter

Claims 4,5,7 are allowable over the prior art of record.

Claims 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 2/27/06 have been fully considered but they are not persuasive. With respect to claim 20, the orifice provides an open unsealed space over the skin until the squeeze bulb is actuated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS